IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

(Attorney Docket No. 006401.00371)

| In re U.S. Patent Application of |) |
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| Wang et al. |) |
| |) |
| Application No.: 09/863,928 |) |
| |) Group Art Unit: 1732 |
| Filed: May 23, 2001 |) |
| • |) Examiner: Monica A. Huson |
| For: COLD WATER SOLUBLE |) |
| EXTRUDED STARCH |) Confirmation No. 1613 |
| PRODUCT |) |
| |) |
| | |

Commissioner of Patents P.O. Box 1450 Alexandria, VA 22313-1450

APPEAL BRIEF

This constitutes applicants' brief on appeal. The information specified by 37 C.F.R. 41.37 (c)(1) is provided hereunder.

Real Party In Interest

The real party in interest in this application is Grain Processing Corporation of Muscatine, Iowa, the assignee.

Related Appeals and Interference

None known.

Status of Claims

The pending claims include claims 1-43. Of these, claims 8-32 have been withdrawn from consideration. Accordingly, claims 1-7 and 33-43 are presented for appeal. The independent claims 1 and 33.

Status of Amendments

No amendments have been filed subsequent to final rejection.

Summary of Claimed Subject Matter

Claims 1, and those claims that depend therefrom, are directed towards a process for preparing a cold-water soluble extruded starch product. The starch product so prepared has a solubility greater than 90% in water at 25°C. Additionally, the extruded starch product is film-forming in aqueous solution and is gelatinized to a gelatinization level of at least 95%.

As specified in claim 1, the process comprises extruding the starch in an extruder. The extruder has a barrel, a die, and at least one rotating shaft. The barrel has at least first and second zones, the first zone being upstream from the second zone. As specified in claim 1, the conditions of the first zone are insufficient to gelatinize the starch to the requisite gelatinization level, but the conditions in the second zone are sufficient to gelatinize the starch to the gelatinization level.

Claim 33 is directed towards a process for preparing a coated food product. This process comprises providing a food substrate, providing a seasoning adherence solution, and applying the seasoning adherence solution to the food product. The seasoning adherence solution comprises an extruded starch product and a seasoning, the extruded starch product having been prepared in an extruder, under conditions similar to those specified in claim 1.

Grounds of Rejection to be Reviewed on Appeal

The final Office Action contains only one ground of rejection. The pending claims stand as rejected under 35 U.S.C. §103 over three references, Nakatsuka et al., U.S. patent 4,076,846, in view of Redding, Jr., U.S. patent 5,455,342, and further in view of Altieri, U.S. patent 5,849,233. For claim 7, a fourth reference (Protzman, U.S. patent 3,137,592) is applied. Accordingly, the grounds of rejection to be reviewed on appeal are as follows:

- None of the cited references disclose or suggest extruding starch under the conditions claimed to form a soluble starch product. In light of the foregoing, did the Examiner err in rejecting the claims?
- With respect to claim 33, and those claims that depend therefrom, none of the cited references disclose a seasoning adherence solution. In light of the foregoing, did the Examiner err in rejecting the subject claims?

Argument

The rejection relies primarily on the Nakatsuka reference, which the Examiner asserts contains a disclosure of extrusion conditions and a disclosure of a soluble starch product prepared upon extrusion. As discussed below, the Examiner is in error in relying on this reference. Moreover, the secondary references, Altieri and Redding, Jr., cannot fairly be combined with the Nakatsuka reference. The section 103 rejection is markedly deficient, and must be reversed.

<u>Ground 1 – Applicable to All Claims</u>

The claims specify the following elements:

- A starch is extruded to form a **starch product**.
- The starch product is **soluble** (greater than 95%) at 25° C.
- The starch is (or has been) extruded in an extruder with **two zones**. The conditions in the first zone are insufficient to gelatinize the starch, but the conditions in the second zone are sufficient to gelatinize the starch.
- The **moisture content** in the extruder barrel is no greater than about 25% by weight of the starch.
- The **particle size** of the granular starch is such that at least 90% of the starch particles pass through a 180 micron screen.

The Examiner asserts, erroneously, that the starch product, solubility, and two extruder zones may be found in Nakatsuka. The Examiner is wrong.

Nakatsuka is deficient

First, Nakatsuka cannot be relied on for any teaching of a starch product resulting from extrusion. Nakatsuka is directed towards the preparation of a complex of starch with protein. This complex, according to Nakatsuka, "is not a simple mixture," but rather, "it seems that some degree of union has been established between both materials by chemical reaction, thus contributing to the improvement in physical properties." Col. 6, lines 34-40. Nakatsuka does not specify the nature of this product. Is it a starch? Is it a protein? Does the resulting material have any polymeric carbohydrate structure? Nakatsuka does not say, and this detail is unclear. Given this deficiency in the disclosure, it is not proper to rely on Nakatsuka to disclose a starch product. Accordingly, the rejection fails on this ground alone.

In the Advisory Action, the Examiner, citing to the Nakatsuka patent, states "Nakatsuka makes several references to the unmodified nature of starches used in his invention." This is simply wrong. In the places cited by the Examiner, Nakatsuka is referring to a **starting material**, not the material that results upon extrusion. Nowhere does Nakatsuka state that starch alone is extruded, or that something other than a starch-protein product is prepared.

Second, the claims of the present application specify that the extruded starch product has a solubility greater than 90% in water at 25°C. This limitation likewise is not found with certainty in Nakatsuka. Nakatsuka states generally that his product has some water solubility, but does not teach a solubility greater than 90% in water at 25°C. The Examiner points to Table 2, but the claimed solubility is not seen in this Table. Table 2 does contain some solubility data, but the meaning of this data is not clear. The Examiner has chosen to construe this data as a listing of number of seconds required for the starch-protein complex to dissolve at the specified temperature ranges. Even if it were accurate to so construe this data (and this is far from certain, given the paucity of Natatsuka's disclosure), it is not clear that this represents dissolution to the extent of *at least 90%*. In the same column, at line 53, Nakatsuka describes an embodiment in which the product was said to *swell*, not dissolve. Additionally, at column 10, lines 37-56, Nakatsuka teaches that a "protein coagulant" may be added to vary the degree of solubility. This passage indicates by implication that the product is not completely soluble under some

circumstances. Again, although Nakatsuka provides some disclosure, the reference lacks the requisite certainty to support a Section 103 rejection.

Perhaps the most fundamental defect in Nakatsuka, however, is that Nakatsuka fails to teach extruding the starch in an extruder having two zones, the conditions in the first zone being insufficient to gelatinize the starch to the specified gelatinization level of at least 95%, but the conditions of the second zone being sufficient to gelatinize starch to this gelatinization level. At page 3 of the Office Action, the Examiner points to column 9, lines 9-17, 31-33, and 49-53; col. 13, lines 31-40, and col. 14, lines 5-12 and 25-28. Among these teachings, the only teaching of what might be deemed to be multiple zones is at col. 13, lines 31-40, where, in an injection molding machine, the following conditions are specified:

Temperature inside the barrel; the 30°C to 50°C (water cooling) at the part below the hopper 120°C to 160°C at middle part, 160°C to 200°C at front part.

To form the rejection, the Examiner asserts (at page 3 of the Office Action) that "it is noted that gelatinization occurs about 150°C to 175°C."

The Examiner is incorrect on multiple grounds. First, because the nature of the Nakatsuka material is unclear, it is uncertain whether this material even has a gelatinization temperature, or is capable of gelatinization. Second, even if the material of Nakatsuka could be deemed a "starch," how does the Examiner know what the gelatinization temperature of this starch would be? The Examiner does not say. Third, if gelatinization occurs at "about 150°C" as asserted by the Examiner, presumably gelatinization would occur at **both** the "middle part" and the "front part," because a temperature of 160° C – above the Examiner's asserted gelatinization temperature – may be present in either "part." Nakatsuka's failure to meet this claim limitation is yet another, independent ground that requires reversal.

Nakatsuka is the sole reference relied on for these features of the claimed invention. Given that Nakatsuka fails to teach these features, the rejection should be withdrawn for the foregoing reasons alone.

The references are improperly combined

Even if the Board were to overlook all of the foregoing, however, the rejection still must be reversed. The Examiner has relied on a combination of Nakatsuka with Altieri and Redding, Jr., and both combinations are improper.

For the moisture content limitation of the claims, the Examiner acknowledges that "Nakatsuka does not specifically show barrel moisture level." (Final Office Action, page 3). For this, the Examiner relies on the Altieri reference. But the Examiner is reading Altieri in a vacuum, and is ignoring other parts of the claimed invention, specifically, the particle size limitation of the claims. As stated above, the claims specify that the starch that is provided to the extruder is a granular starch that has a particle size distribution such that at least 90% by weight of the starch particles pass through a 180 microns screen. Altieri teaches that, in his process, it is necessary to use starch "chunks" that are of a significantly larger particle size. See, col. 2, lines 23-40 and Examples 1 and 2. In Altieri's Example 1, it is revealed that the starch "chunks" are sized such that over 70% are retained on an 80 mesh screen (80 mesh corresponds to 180 microns). See col. 6, line 5. In Example 2, a comparative example, a starch having a smaller size was employed, and, in Example 3, this starch is reported as being unsatisfactory (the extrusion is indicated as being "unstable.")

Given these contrary teachings, Altieri is not useful in connection with a section 103 rejection. The Examiner is completely ignoring these contrary teachings, and, to make the rejection, she has reach into this reference for support for one claim limitation while ignoring the overall teachings of the reference. This is classic hindsight reasoning, and must be reversed.

Additionally, the Examiner relies on the Redding, Jr. reference for a teaching of the claimed particle size. Again, the Examiner is grasping at straws, choosing favorable language while ignoring the contrary teachings of this reference. In asserting that the Nakatsuka and Redding, Jr. references are combinable, the Examiner states that "Redding, Jr. and Nakatsuka are combinable because they are concerned with a similar technical field, namely, methods of molded starches." Only in hindsight could this conclusion be reached. Nakatsuka is concerned with a starch that is heavily modified in a starch-protein complex, perhaps to the extent of the loss of the starch structure. Redding, on the other hand, teaches that chemical starch modification is undesirable. See col. 2. line 39 et seq. Redding, Jr. states as an object of his invention "to provide a cost effective and an energy efficient method of physical modification of

starch and other substrates *without the necessity of chemical additives* required by prior art processes" (emphasis added). According to the subject matter purportedly taught by this patent, instead of making chemical modifications to the starch, the starch should be subjected to an abrupt pressure change by using a piston-type apparatus.

With respect to claim 7, the Protzman reference, U.S. patent 3,137,592, does not add anything to overcome the deficiencies of the cited art.

In summary, to arrive at the section 103 of claim 1, the Examiner has disregarded the teachings in Nakatsuka as to the nature of the extruded product. She has mistakenly pointed to passages in Nakatsuka that pertain to the starting material, not the extruded product. The Examiner has further ignored the fact that Nakatsuka fails to teach the solubility data specified in the claims. Additionally, she has ignored the fact that Nakatsuka fails to teach the extrusion conditions specified in the claims. After this inauspicious start, the Examiner then reaches into the Altieri reference, while ignoring the fact that the Altieri reference teaches that the particle size specified in the claims is inoperative. The Examiner concludes with an improper citation to Redding, Jr., which teaches — directly in contrast to the teachings of Nakatsuka — that that chemical modification of starch should be avoided. The Examiner's line of reasoning is wholly improper. She relies on a misconstruction of the Nakatsuka reference, and on a hindsight reconstruction of the invention from disparate, incompatible references that she has cobbled together. The rejection of all claims must be reversed.

Ground 2 – Claim 33 and those claims that depend therefrom

With respect to the subject claims, the foregoing arguments apply with full force. In addition, claim 33 is directed towards a process for preparing a coated food product with a seasoning adherence solution. The seasoning adherence solution comprises a starch and a seasoning, and, in accordance with the process of claim 33, this solution applied to a food product.

The Examiner purports to find these teachings in Nakatsuka. But this reference teaches that the extruded starch-protein complex is a "shaped article," not a solution. This "shaped article" is said to be useful as a **packaging material**. Nakatsuka fails to disclose forming a solution from the shaped article, much less that Nakatsuka disclose or suggest forming a

seasoning adherence solution and applying it to food. The Examiner is simply off the mark in

finding a seasoning adherence solution in Nakatsuka.

In the Advisory Action, the Examiner points to Nakatsuka at col. 11, lines 1-61 for these

teachings. There is no teaching or suggestion in this passage of a seasoning adherence solution.

Rather, this passage discloses only a package.

In the advisory action, the Examiner states "it is being interpreted that when packaged,

the extruded seasoning article is adhered, at least temporarily, to the food substrate." The

Examiner here points particularly to col. 11, lines 44-47. But claim 33, does not merely specify

food in contact with extruded starch. This claim specifies a seasoning adherence solution, not a

package. Nakatsuka fails to disclose any such solution, in lines 44 to 47 or elsewhere. The

rejection is not proper, and must be reversed.

Conclusion

For these reasons, the rejections entered in the Final Rejection cannot stand. Reversal of

the claim rejections is respectfully solicited.

Respectfully submitted,

Date: November 1, 2006

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Claims Appendix

1. (Previously presented) A process for preparing a cold-water soluble extruded starch product that has a solubility greater than 90% in water at 25° C that is film-forming in aqueous solution and that is gelatinized to a gelatinization level, said gelatinization level being at least 95%, the process comprising:

providing a hydroxyalkyl starch, said starch being derivatized with a hydroxyalkyl substituent having from 2 to 6 carbon atoms, said starch being a granular starch having a particle size distribution such that at least 90% by weight of the starch particles pass through a 180 micron screen; and

extruding said starch in an extruder, said extruder having a barrel, a die, and at least one rotating shaft, said barrel having at least first and second zones, said first zone being upstream from said second zone, the conditions in said first zone being insufficient to gelatinize said starch to said gelatinization level and the conditions in said second zone being sufficient to gelatinize said starch to said gelatinization level, said starch being extruded in the presence of total moisture in said barrel no greater than about 25% by weight of said starch, said process including the step of controlling the rotational speed of said shaft to impart a specific mechanical energy to said starch sufficient to result in a soluble extruded starch product that is capable of extrusion through said die at said rotational speed.

- 2. (Original) A process according to claim 1, the moisture in said barrel not exceeding 22.5% by weight of said starch.
- 3. (Original) A process according to claim 1, the moisture in said barrel not exceeding 20% by weight of said starch.
- 4. (Original) A process according to claim 1, the moisture in said barrel not exceeding 17.5% by weight of said starch.
- 5. (Original) A process according to claim 1, further comprising the step of drying said extruded starch product to a moisture content below about 15% to form a dried product.

- 6. (Original) A process according to claim 5, said starch product being dried to a moisture content between about 9% and about 12%.
- 7. (Original) A process according to claim 6, further comprising the step of grinding said dried product.
 - 8. (Withdrawn) An extruded starch product prepared by a process comprising:

providing a hydroxyalkyl starch, said starch being derivatized with a hydroxyalkyl substituent having from 2 to 6 carbon atoms; and

extruding said starch in an extruder, said extruder having a barrel, a die, and at least one rotating shaft, said barrel having at least first and second zones, said first zone being upstream from said second zone, the temperature in said first zone being insufficient to gelatinize said starch and the temperature in said second zone being sufficient to gelatinize said starch, said starch being extruded in the presence of total moisture in said barrel no greater than about 25% by weight of said starch, said process including the step of controlling the rotational speed of said shaft to impart a specific mechanical energy to said starch sufficient to result in a soluble extruded starch product that is capable of extrusion through said die at said rotational speed, said starch being substantially completely soluble in water at 25° C and being film-forming in aqueous solution.

- 9. (Withdrawn) A starch according to claim 8, said starch having a moisture content below about 15%.
- 10. (Withdrawn) A starch according to claim 8, said starch having a moisture content ranging from about 9% to about 12%.
- 11. (Withdrawn) A process for preparing a solution of an extruded starch product, comprising:

providing a hydroxyalkyl starch, said starch being derivatized with a hydroxyalkyl substituent having from 2 to 6 carbon atoms;

extruding said starch in an extruder, said extruder having a barrel, a die, and at least one rotating shaft, said barrel having at least first and second zones, said first zone being upstream from said second zone, the temperature in said first zone being insufficient to gelatinize said starch and the temperature in said second zone being sufficient to gelatinize said starch, said

starch being extruded in the presence of total moisture in said barrel no greater than about 25% by weight of said starch, said process including the step of controlling the rotational speed of said shaft to impart a specific mechanical energy to said starch sufficient to result in a soluble extruded starch product that is capable of extrusion through said die at said rotational speed; and mixing said extruded starch product with water.

- 12. (Withdrawn) A process according to claim 11, the moisture in said barrel not having exceeded 22.5% by weight of said starch.
- 13. (Withdrawn) A process according to claim 11, the moisture in said barrel not having exceeded 20% by weight of said starch.
- 14. (Withdrawn) A process according to claim 11, the moisture in said barrel not having exceeded 17.5% by weight of said starch.
- 15. (Withdrawn) A process according to claim 5, said product being present in said solution in an amount ranging from 1% to 40% on a dry basis.
- 16. (Withdrawn) A process for preparing a solution of an extruded starch product, comprising:

providing an extruded starch product, said product having been prepared by a process comprising:

providing a hydroxyalkyl starch, said starch being derivatized with a hydroxyalkyl substituent having from 2 to 6 carbon atoms;

extruding said starch in an extruder, said extruder having a barrel, a die, and at least one rotating shaft, said barrel having at least first and second zones, said first zone being upstream from said second zone, the temperature in said first zone being insufficient to gelatinize said starch and the temperature in said second zone being sufficient to gelatinize said starch, said starching being extruded in the presence of total moisture in said barrel no greater than about 25% by weight of said starch, said process including the step of controlling the rotational speed of said shaft to impart a specific mechanical energy to said starch sufficient to result in a soluble extruded starch product that is capable of extrusion through said die at said rotational speed; and mixing said extruded starch product with water.

17. (Withdrawn) A process according to claim 16, the moisture in said barrel not having exceeded 22.5% by weight of said starch.

- 18. (Withdrawn) A process according to claim 16, the moisture in said barrel not having exceeded 20% by weight of said starch.
- 19. (Withdrawn) A process according to claim 16, the moisture in said barrel not having exceeded 17.5% by weight of said starch.
- 20. (Withdrawn) A process according to claim 16, said product being present in solution in an amount ranging from 1 % to 40% on a dry basis.
 - 21. (Withdrawn) The solution formed in accordance with the process of claim 20.
 - 22. (Withdrawn) A process for preparing a film, comprising:

providing a solution of an extruded starch product, said starch product having been prepared by a process comprising

providing a hydroxyalkyl starch, said starch being derivatized with a hydroxyalkyl substituent having from 2 to 6 carbon atoms; and

extruding said starch in an extruder, said extruder having a barrel, a die, and at least one rotating shaft, said barrel having at least first and second zones, said first zone being upstream from said second zone, the temperature in said first zone being insufficient to gelatinize said starch and the temperature in said second zone being sufficient to gelatinize said starch, said starch being extruded in the presence of total moisture in said barrel no greater than about 25% by weight of said starch, said process including the step of controlling the rotational speed of said shaft to impart a specific mechanical energy to said starch sufficient to result in a soluble extruded starch product that is capable of extrusion through said die at said rotational speed;

said solution having been prepared by mixing said starch product with water; and forming a film from said solution.

- 23. (Withdrawn) A process according to claim 22, the moisture in said barrel not having exceeded 22.5% by weight of said starch.
- 24. (Withdrawn) A process according to claim 22, the moisture in said barrel not having exceeded 20% by weight of said starch.
- 25. (Withdrawn) A process according to claim 22, the moisture in said barrel not having exceeded 17.5% by weight of said starch.
- 26. (Withdrawn) A process according to claim 22, wherein said solution includes a plasticizer.

- 27. (Withdrawn) A film formed in accordance with the process of claim 22.
- 28. (Withdrawn) A process for preparing a seasoning adherence solution, comprising:

mixing water, an extruded starch product, and a seasoning to form a seasoning adherence solution, said extruded starch product having been formed by a process comprising:

providing a hydroxyalkyl starch, said starch being derivatized with a hydroxyalkyl substituent having from 2 to 6 carbon atoms; and

extruding said starch in an extruder, said extruder having a barrel, a die, and at least one rotating shaft, said barrel having at least first and second zones, said first zone being upstream from said second zone, the temperature in said first zone being insufficient to gelatinize said starch and the temperature in said second zone being sufficient to gelatinize said starch, said starch being extruded in the presence of total moisture in said barrel no greater than about 25% by weight of said starch, said process including the step of controlling the rotational speed of said shaft to impart a specific mechanical energy to said starch sufficient to result in a soluble extruded starch product that is capable of extrusion through said die at said rotational speed.

- 29. (Withdrawn) A process according to claim 28, the moisture in said barrel not having exceeded 22.5% by weight of said starch.
- 30. (Withdrawn) A process according to claim 28, the moisture in said barrel not having exceeded 20% by weight of said starch.
- 31. (Withdrawn) A process according to claim 28, the moisture in said barrel not having exceeded 17.5% by weight of said starch.
- 32. (Withdrawn) The seasoning adherence solution prepared in accordance with claim 28.
 - 33. (Previously presented) A process for preparing a coated food product, comprising: providing a food substrate; providing a seasoning adherence solution; and

applying said seasoning adherence solution to said food product in a manner effective to cause seasoning in said solution to adhere to said food substrate; said seasoning adherence solution having been prepared by mixing water, an extruded starch product, and a seasoning to form said solution, said product having been formed by a process comprising:

providing a hydroxyalkyl starch, said starch being derivatized with a hydroxyalkyl substituent having from 2 to 6 carbon atoms, said starch being a granular starch having a particle size distribution such that at least 90% by weight of the starch particles pass through a 180 micron screen; and

extruding said starch in an extruder, said extruder having a barrel, a die, and at least one rotating shaft, said barrel having at least first and second zones, said first zone being upstream from said second zone, the conditions in said first zone being insufficient to gelatinize said starch to a gelatinization level of 95% and the conditions in said second zone being sufficient to gelatinize said starch to a gelatinization level of 95%, said starch being extruded in the presence of total moisture in said barrel no greater than about 25% by weight of said starch, said process including the step of controlling the rotational speed of said shaft to impart a specific mechanical energy to said starch sufficient to result in a soluble an extruded starch product that has a solubility greater than 90% in water at 25° C and that is capable of extrusion through said die at said rotational speed.

- 34. (Original) A process according to claim 33, the moisture in said barrel not having exceeded 22.5% by weight of said starch.
- 35. (Original) A process according to claim 33, the moisture in said barrel not having exceeded 20% by weight of said starch.
- 36. (Original) A process according to claim 33, the moisture in said barrel not having exceeded 17.5% by weight of said starch.
- 37. (Previously presented) A process according to claim 1, said starch having a solubility of at least 99% in water at 25° C.
- 38. (Previously presented) A process according to claim 33, said starch having a solubility of at least 99% in water at 25° C.

39. (Previously presented) A process for preparing a cold-water soluble extruded starch product that has a solubility greater than 90% in water at 25° C, that is film-forming in aqueous solution, and that is gelatinized to a gelatinization level, said gelatinization level being at least 95%, the process comprising:

providing a hydroxyalkyl starch, said starch being derivatized with a hydroxyalkyl substituent having from 2 to 6 carbon atoms, said starch being a granular starch having a particle size distribution such that at least 90% by weight of the starch particles pass through a 180 micron screen; and

extruding said starch in an extruder, said extruder having a barrel, a die, and at least one rotating shaft, said process including the step of controlling the rotational speed of said shaft to impart a specific mechanical energy to said starch sufficient to result in a soluble extruded starch product that is capable of extrusion through said die at said rotational speed.

- 40. (Previously presented) A process according to claim 39, said barrel having at least first and second zones, said first zone being upstream from said second zone, the conditions in said first zone being insufficient to gelatinize said starch to said gelatinization level and the conditions in said second zone being sufficient to gelatinize said starch to said gelatinization level.
- 41. (Previously presented) A process according to claim 1, said hydroxyalkyl starch comprising a hydroxypropyl starch.
- 42. (Previously presented) A process according to claim 3, said hydroxyalkyl starch comprising a hydroxypropyl starch.
- 43. (Previously presented) A process according to claim 39, said starch comprising a hydroxypropyl starch.

| Evidence Appendi |
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None.

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None.